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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/405,839	09/27/99	BRIGHT	S PM-263754

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PILLSBURY MADISON & SUTRO LLP
INTELLECTUAL PROPERTY GROUP
1100 NEW YORK AVENUE NW
9TH FLOOR EAST TOWER
WASHINGTON DC 20005-3918

EXAMINER .

BUTLER, T
ART UNIT PAPER NUMBER

1636

DATE MAILED:

02/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/405,839

Applicant(s)

BRIGHT ET AL.

Examiner

Thomas Butler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 1999 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

The Declaration of Didier Thomas appears to be directed against a rejection made in the abandoned parent application (08/374783). However, the examiner has reviewed the contents of the Declaration and the data cited therein.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Drawings

The drawings are objected to because Figure 11 is improperly labeled as Figure 10. Thus, there are two figures designated as Figure 10. Correction is required.

Specification

This application is informal in the arrangement of the specification. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 - 1. Field of the Invention.

2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
 - (f) Brief Summary of the Invention.
 - (g) Brief Description of the Several Views of the Drawing(s).
 - (h) Detailed Description of the Invention.
 - (i) Claim or Claims (commencing on a separate sheet).
 - (j) Abstract of the Disclosure (commencing on a separate sheet).
 - (k) Drawings.
 - (l) Sequence Listing (see 37 CFR 1.821-1.825).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a recombinant DNA construct functional in a plant comprising the malate synthase promoter sequence functionally linked to the barnase gene and an inducible promoter sequence functionally linked to the barstar gene and plants and plant seed transformed with said recombinant DNA construct, does not reasonably provide enablement for other plant developmental gene promoters and other disrupter/inhibitor genes that can be used to regulate a plant development phenotype. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant claims an expression system functional in a plant comprising an inducible promoter sequence, a repressor protein sequence or an inhibitory gene, a plant developmental gene promoter, and a protein-disrupter gene. Applicant also claims plants, plant seed, and plant

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germplasm transformed with said expression system where germination of the transformants is regulated by an exogenous chemical inducer. Claims are made to said expression system comprising specific inducible gene promoter sequences, specific repressor/inhibitor genes, specific plant development gene promoters, and specific protein disrupter genes.

Applicant teaches a recombinant DNA construct (pPOP1) comprising the malate synthase gene promoter functionally linked to the barnase/barstar genes and the safener-inducer GSTII-27 gene promoter functionally linked to the barstar gene. Applicant also teaches a recombinant DNA construct, pSWEI, comprising the malate synthase gene promoter functionally linked to the FLP gene, which is linked to the lacI gene. A gene construct was made by fusion of the CaMV35s promoter, the PAT gene flanked by FRT recombinase sites, and glucuronidase (GUS). The fusion construct was introduced into a unique NotI site in the SWE1 vector. Applicant teaches transformation of tobacco with SWE1 fusion construct. Applicant teaches the effects of safener on seed germination and GUS expression. About 50% of the seed germinate without safener whereas 90-100% germinate in the presence of safener. Applicant does not teach other recombinant gene constructs, plants transformed with said constructs, or effects on other stages of plant development other than seed germination.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The state of the art for modification of gene expression or of phenotypic characteristics in plants by genetic transformation is highly unpredictable and hence significant guidance is required to practice the art without undue experimentation. The specific effects of given promoters, leaders, DNA sequences, and terminator sequences on gene expression in transformed plants can not be anticipated reliably and must be determined empirically (Plant Mol. Biol. 32:393-405, 1996, abstract, pp. 402-403). In genetically modified plants, the introduced transgenes are sometimes not expressed and they can also result in co-suppression effects. None of these effects are predictable and the mechanisms of gene silencing are still not fully understood (Ann. Bot. 79:3-12, 1997, abstract, p. 9). Moreover, the phenotypic characteristic that will result from expression of a given DNA construct can not be reliably predicted. Often the expected phenotypic result is not achieved. For example, antisense expression of the polygalacturonase gene in transgenic tomato had no effect on fruit softening (Nature 334:724-726, 1988, p. 725).

Given the unpredictability in the art, the instant invention is not enabled for the full scope of the claims given the lack of guidance in the specification with regard to what plant developmental gene promoters other than the malate synthase promoter, and what disrupter/inhibitor genes other than the barnase/ barstar genes can be used in the invention to effect a plant development phenotype other than seed germination in transgenic plants. Applicant teaches only how to transform tobacco plants with the disclosed DNA constructs and suggests other gene promoters and coding sequences that could be used. However, it is not clear that the suggested plant developmental gene promoters or disrupter/inhibitor genes have in fact been isolated and shown to be active in transgenic plants. Furthermore, applicant has not shown

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that transgenic plants transformed with constructs comprising other gene promoters and coding sequences have a defined plant development phenotype that can be regulated by application of an inducer substance. In particular, the effects of antisense or sense suppression sequences are highly unpredictable as discussed above. Given the unpredictability of specific promoter/gene sequences in transgenic plants, and in particular as in the instant invention where multiple gene cassettes are introduced whose gene products are intended to interact with one another, significant guidance is required to practice the invention. Applicant has provided only one working example and in the absence of additional empirical evidence, undue trial and error experimentation would be required to screen through the vast number of different combinations of gene promoters, gene disrupters/inhibitors, plant development genes, DNA constructs and transgenic plants to determine how to modify seed germination or other plant phenotypes, and to regulate said phenotypes with an exogenous chemical inducer. When the Wands factors are weighed it is concluded that undue experimentation would be required to practice the invention throughout the full scope of the claims. Therefore, the invention is not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 states "...selected stage of plant development..." which is indefinite because it is not clear on what basis the stage is selected and hence what is encompassed by the claim.

Claim 26 states "...plant characteristic is either essential to plant growth or is a desired characteristic..." There are many different plant characteristics which are essential to plant growth. There are even more plant characteristics that are not essential to plant growth so it is not clear what is encompassed by "...desired characteristic..." Applicant should amend the claim to more clearly define the metes and bounds of the claimed invention.

Claim 27 states "...plant characteristic... is essential to plant growth..." which is indefinite because there are many different plant characteristics that are essential to plant growth, thus it is not clear what is encompassed by the claim. Applicant should amend the claim to more clearly define the metes and bounds of the claimed invention.

Claim 27 states "...selected stage of plant development..." which is indefinite because it is not clear on what basis the stage is selected and hence what is encompassed by the claim.

Claim 27 states "...allows either growth to maturity or causes growth to slow down or stop..." which is indefinite because it is unclear whether the claim is directed to a gene construct which enhances growth or inhibits growth.

Claim 29 states "...a cytotoxin which disrupts cell function, leading to cell death." The specification teaches a gene construct that regulates seed germination and plant growth or a plant characteristic. The cytotoxin will only cause the death of the seed or plant not regulate it per se, therefor it is unclear as to how the cytotoxin can regulate growth and/or development.

Claim 31 states " ...the disrupter gene encodes a nucleotide sequence adapted to inhibit an endogenous plant gene..." which is indefinite because a gene does not encode a gene and a gene does not inhibit a gene. It is also unclear as to how the nucleotide sequence is

"...adapted..." It is also unclear as to whether the endogenous plant gene is part of the recombinant DNA construct or if it is found in the plant genome.

Claim 31 states "...is essential to plant development..." which is indefinite because there are many different endogenous plant genes that are essential to plant development, thus it is unclear as to what is exactly claimed by the invention. Applicant should more clearly define the metes and bounds of the claimed invention.

Claim 31 states "...conferring a desired characteristic on the plant." The claim fails to point out what the desired characteristic is among the many characteristics that a plant may display. The metes and bounds of the claimed invention must be more clearly defined.

Claim 33 states "...endogenous plant gene." It is unclear as to whether the endogenous plant gene is part of the recombinant DNA construct or if it is found in the plant genome.

Claim 35 states "...the promoter of a gene normally active during germination or early seedling development." It is not known what is encompassed by the claim because many promoters are active during germination or early seedling development and it is not known what promoters are intended by the Applicant. Applicant should amend the claim to more clearly define the metes and bounds of the claimed invention.

Claim 38 states "...aleutrone..." which is unclear because "aleutrone" is not a known substance.

Claims 39 and 40 state "...an inserted gene." The claim is indefinite because the "inserted gene" is undefined. Therefore, it is unclear as to what gene/s are encompassed by the claim. Applicant should amend the claim to more clearly define the metes and bounds of the claimed invention.

Claim 46 states "...bamase.." which is vague and indefinite because "bamase" is not a known substance.

Claim 47 states "...recombinant plant genome..." which is unclear because there are no recombinant genomes nor do the specifications teach a "recombinant plant genome." Therefore, it is unclear as to what is claimed.

Claims 48-50 state "...a recombinant genome..." which is unclear because there are no recombinant genomes nor do the specifications teach a "recombinant genome." Therefore, it is unclear as to what is claimed.

Claim 51 states "protected plant germplasm comprising a plant." It is unclear how the germplasm is protected. Also, it is unclear how a plant germplasm can comprise a plant.

Claim 52 states "A plant or seed...incapable of growing to maturity comprising a genome which includes a genetic inhibitor of seed germination or plant development...inhibitor being regulatable." If the seed or plant is incapable of growing to maturity then it is unclear as to why a regulatable inhibitor of seed germination or plant development is necessary.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-28, 35, and 42, 47-50 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bridges et al (WO 90/08830). Bridges teaches a recombinant gene construct comprising a promoter that is specific to male flowers operably linked to an inhibitor gene (abstract, p. 6-11). Bridges teaches the inducible GST-II promoter (p. 19-21), and also teaches a male flower specific promoter that accumulates early in tassel development (pp. 65-66). Therefore, Bridges has disclosed all of the claim limitations. The promoter taught by Bridges is both anther-specific and development-specific. The prior art of Bridges either anticipates the claimed invention or is obvious over the claimed invention because it would have been obvious to one of ordinary skill in the art to substitute a development-specific promoter for the tissue-specific/development-specific promoter taught by Bridges. The two promoters are functional equivalents and it would have been obvious to one of ordinary skill in the art to substitute one functional equivalent for another. One would have been motivated to do so if growth and development at a particular stage of development, and not necessarily in a particular tissue was desired and one would have had a reasonable expectation of success given the success of Bridges.

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Butler whose telephone number is (703) 308-8361. The examiner can normally be reached on (703) 308-8361 from 8:30am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Schwartz, can be reached on (703) 308-1133. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Zeta Adams whose telephone number is (703) 305-3291.


Thomas Butler

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DAVID GUZO
PRIMARY EXAMINER
